

EXHIBIT 5

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APPLICATION NUMBER: 14/103,324

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Certified by

Kathi

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Appln. No.: 14/103,324
Amendment Dated March 7, 2016
Reply to Office Action of December 7, 2015

TEVE-139US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 14/103,324
Applicant: Declan Walsh et al.
Filed: December 11, 2013
Title: DOSE COUNTERS FOR INHALERS, INHALERS AND
METHODS OF ASSEMBLY THEREOF
T.C./A.U.: 2876
Examiner: Daniel A. Hess
Confirmation No.: 3830
Docket No.: TEVE-139US1

AMENDMENT UNDER 37 C.F.R. § 1.116

Expedited Procedure

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Responsive to the Final Office Action dated December 7, 2015, please amend the above-identified application as follows:

- ☐ **Amendments to the Specification** begin on page _____ of this paper.
- ☒ **Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.
- ☐ **Amendments to the Drawings** begin on page _____ of this paper and include an attached replacement sheet(s).
- ☐ **Amendments to the Abstract** are on page _____ of this paper. A clean version of the Abstract is on page _____ of this paper.
- ☒ **Remarks/Arguments** begin on page 4 of this paper.

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Amendments to the Claims: This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister and movable relative thereto, and

a dose counter, ~~the dose counter~~ having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall ~~and located directly adjacent the actuation member, and~~

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.
2. (Previously Presented) The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.
3. (Original) The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.
4. (Original) The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.
5. (Original) The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon.

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6. (Original) The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.
7. (Original) The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.
8. (Original) The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.
9. (Original) The inhaler as claimed in claim 4, wherein the support rail merges with the inner wall at a location adjacent the aperture.
10. (Original) The inhaler as claimed in claim 9, wherein a width dimension of the support rail is not constant, and the width dimension is greatest at the location where the support rail merges with the inner wall.
11. - 20. (Cancelled)

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Remarks/Arguments:

Claim Status

Claims 1-10 are currently pending and stand rejected. Claim 1 has been amended and support for the amendments may be found, *for example*, in the original application at page 11, lines 21 to 27, and in FIGs. 7D and 9. No new matter has been added.

Claim Rejections – 35 USC § 103

Claims 1-10 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Morton et al. (US 2005/0087191) in view of Davies et al. (US 2006/0107949). The Applicant respectfully requests reconsideration of this rejection for the reasons set forth hereinafter.

In establishing a prima facie case of obviousness, “all of the claim limitations must be considered.” M.P.E.P. §2143. Sole independent claim 1 recites features that are neither disclosed nor suggested by the cited references, namely:

An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and ***retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister***, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, ***and***

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X. [Emphasis Added]

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By way of background to the instant invention recited in amended claim 1, the dash-dot line shown below depicts how the inner wall canister support formation 144, the actuation member at 74, and the central outlet port 148 lie in a common plane coincident with the longitudinal axis X at 148.

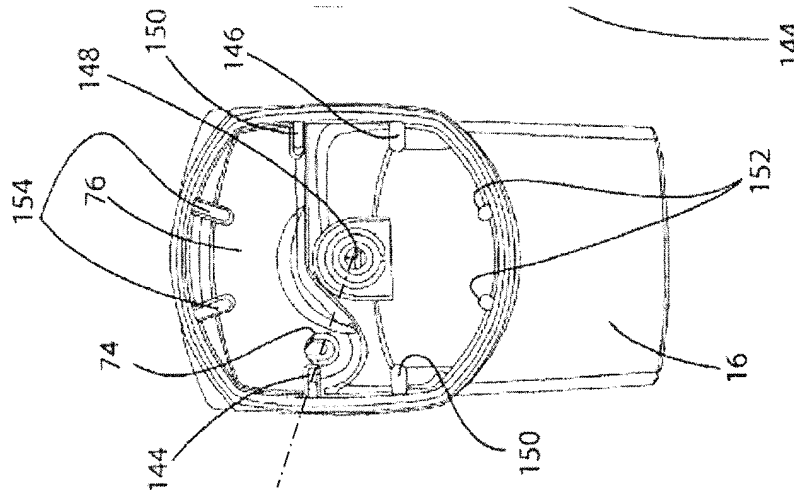


FIG. 7D

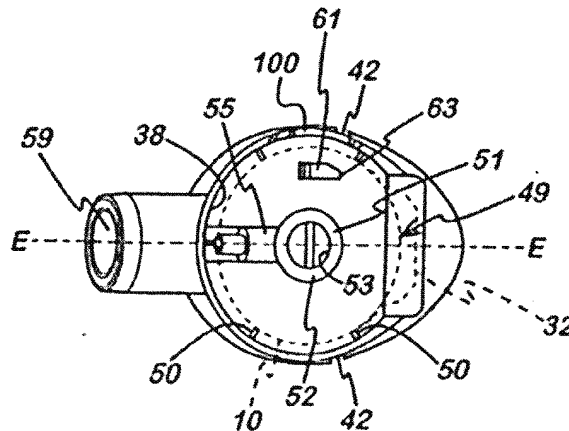
As explained in the instant application, this arrangement is *"highly advantageous in that the first inner wall canister support formation can prevent a canister from rocking too much relative to the main body of the inhaler. Since the canister may operate the actuation member of the dose counter, this substantially improves dose counting and avoids counter errors."* Page 11, lines 16-20. Also, as set forth in the instant application, the claimed arrangement has the advantage of preventing the canister from rocking towards the position of the dose counter actuation member, which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter (see page 11, lines 25-27, and page 27 lines 23-28). It is worth noting that the magnitude of the rocking does not have to be great for it to have a potentially detrimental effect on counter performance. By way of illustration, on page 31, lines 14-15 of the present application, it is disclosed that the distance between the average start and average reset position of such counters may be about 0.7 mm.

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Applicant has discovered that by minimising and/or eliminating the described rocking of the canister in the direction of the actuation member, by way of the specific positioning of a canister support formation relative to the actuator and outlet port, the present invention improves the accuracy of such dose counters. Neither the problem of canister rocking, nor the solution of the specific placement of the canister support formation are taught or suggested by the prior art, which is discussed below.

Turning now to Davies', it is clear that it is not possible to draw a straight line through the center of the stem block (53), the rib (50) and the actuator aperture (61) of FIG. 13 in Davies (below). Accordingly, Davies' inner wall canister support formation, actuation member, and outlet port do not lie in a common plane coincident with the longitudinal axis (near 53). Accordingly, Davies' neither discloses all of the features recited in amended claim 1, nor does Davies' device confer the same benefits as the device that is recited in amended claim 1.



Morton does not disclose the above-identified features of amended claim 1, and the Office Action does not present any arguments to the contrary. Thus, amended claim 1 is not obvious in view of the cited art.

Lastly, the Applicant notes that the Office Action has made the general observation that *"having a gap in the canister housing that is filled by support rails is not functionally better or worse than having a canister housing with less of a gap, more closely conforming to the shape of the housing and obviating the need for the types of rails in the instant invention."* The Applicant disagrees with this statement. Simply conforming the housing to the shape of the canister would increase the airflow resistance of the inhaler and could affect the ability of users with reduced lung function (e.g., the elderly, young or those suffering from an asthma or COPD

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exacerbation) to draw air through the inhaler and inhale medicament effectively. Accordingly, using a body with a greater clearance and accompanying support ribs provides increased design flexibility and a tangible benefit over the approach set forth in the Office Action.

Accordingly, because claim 1 includes features that are neither disclosed nor suggested by the cited references, *prima facie* obviousness cannot be established based on the cited references. The dependent claims that stand rejected should also be allowed at least as being dependent upon an allowable base claim. Reconsideration of claims 1-10 is respectfully requested.

Conclusion

In view of the remarks set forth above, the Applicant respectfully submits that this application is now in condition for allowance, which action is respectfully requested. If the Examiner believes an interview will advance the prosecution of this application, it is respectfully requested that the Examiner contact the undersigned to arrange the same.

Respectfully submitted,

/Brett J. Rosen/

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BJR/mf

Dated: March 7, 2016

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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

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